



# know error<sup>®</sup>

**DNA Testing that brings Patient Safety,  
Confirmation and Confidence to the Diagnostic Process**



*The person in personalized medicine.<sup>®</sup>*



## The Clinical Problem

The biopsy evaluation process requires several steps and medical professionals working in different locations. Each year, it plays a critical role in determining the diagnoses and corresponding treatments of millions of patients.

With such a complex process executed at a large scale, the risk of Specimen Provenance Complications (SPCs) is a serious concern for both physicians and patients. SPCs arise due to instances of specimen transposition, foreign cell contamination and patient misidentification that occur in clinical or anatomical pathology. If left undetected, they can lead to serious diagnostic mistakes and adverse patient outcomes.

## The Innovative Solution

Through the use of bar coding, forensic principles and DNA matching, the **know error® system** brings a higher level of diagnostic accuracy and patient safety to the biopsy evaluation process. Our three step system confirms the identity of the patient's biopsy samples.



1

### Swab

A DNA sample is taken by gently swabbing the inside of each cheek.



2

### Sample

Biopsy tissue sample(s) are placed in bar-coded specimen containers.



3

### DNA Match

A DNA test compares the (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.

### ***What type of biopsy samples use the know error® system?***

Currently, the **know error® system** is conducted on bladder, breast, cervical, colon, endometrial and prostate biopsy samples where well over 100,000 patients have been protected.

### ***Why do we need the patient DNA?***

The DNA plays an important part in the biopsy evaluation process. With a reference sample of DNA (taken via cheek swab at the time of the procedure), physicians using the **know error® system** can confirm that any biopsy samples used in the diagnosis are, in fact, that patient's samples.

### ***What is self-identification?***

Self-identification is an important part in the **know error® system**. We ask for the patient to initial next to their name and patient information on the bar-coded cheek swab bag label. This is the first step to ensure accurate identity.

### ***Will insurance cover the cost of the test?***

In most circumstances, Strand Diagnostics will bill the insurance company. Many insurance companies pay for this test. Please contact our billing specialists at: 888-924-6779, option 1 with any questions. We are here to serve and support throughout the entire process.

# Breast Biopsy Kit Components

The **know error® system** for breast biopsies contains all the necessary components to collect biopsy samples with the added benefit of providing patients the most accurate diagnosis possible.

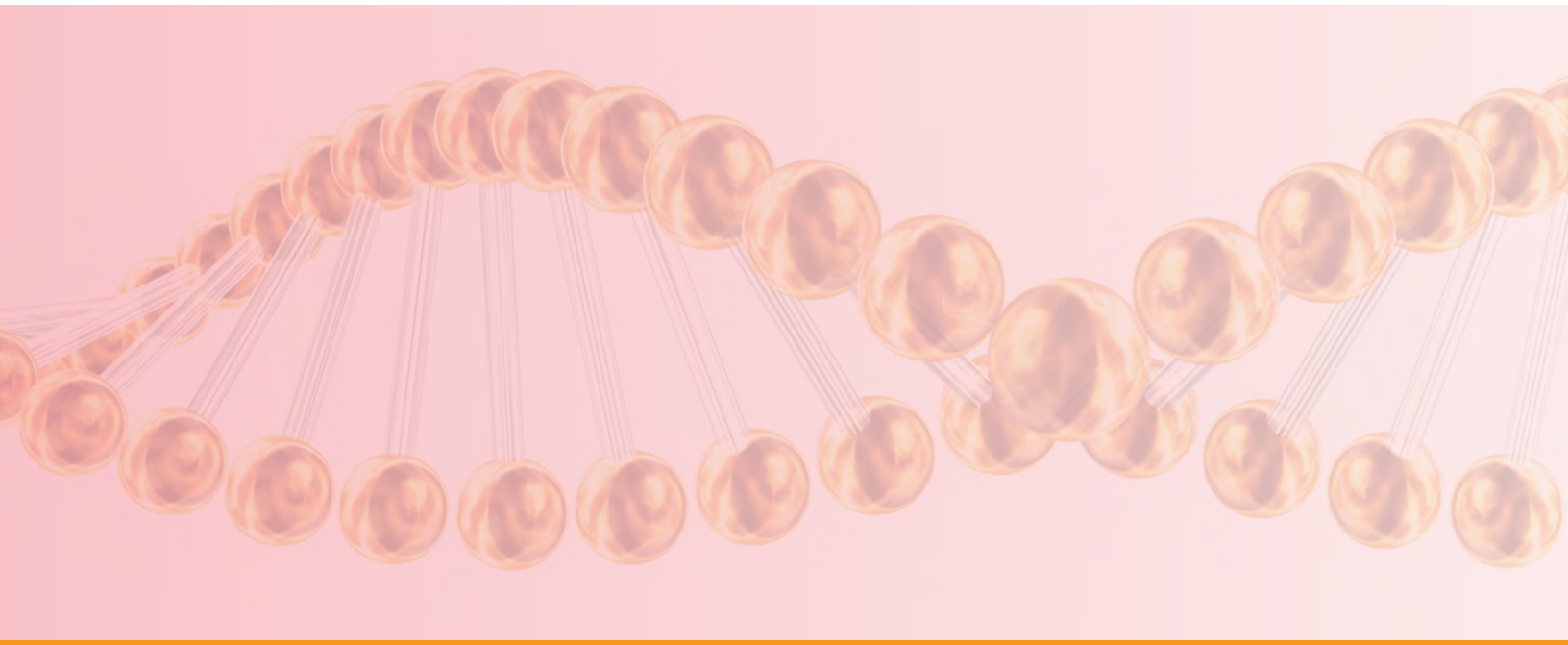


## DNA Report

A DNA Specimen Provenance Assignment (DSPA) report is issued for each patient to summarize the test results. A Know Error representative will contact the appropriate parties immediately if a non-match is detected.

know error		DNA SPECIMEN PROVENANCE ASSIGNMENT REPORT	
		KIT#: AA124566	
<b>PATIENT INFORMATION</b>			
<b>PATIENT</b> <b>Patient S. Name</b> DOB: 11/10/1965		<b>Ordering Physician</b> <b>Dr. Physician Name</b> Date of Service (Biopsy Date): 09/18/2012	
		<b>Physician Practice</b> <b>Radiology of Anywhere</b> Indianapolis, Indiana	
<b>TESTING RESULTS AND INTERPRETATION</b>			
Sample ID	Specimen	Dates	Results
☑ KE: AA124566	Buccal reference	COL: 09/18/12 REC: 09/19/12	<b>Acceptable:</b> A useful profile was produced by this reference sample.
☑ KE: AA124566X CLIENT: 46-8090	Breast	COL: 09/18/12 REC: 09/19/12	<b>Specimen Provenance Verified:</b> The DNA profile from the tissue matches the DNA profile from the reference.
☑ KE: AA124566Y CLIENT: 46-8090	Breast	COL: 09/18/12 REC: 09/19/12	<b>Specimen Provenance Verified:</b> The DNA profile from the tissue matches the DNA profile from the reference.
<b>CASE COMMENTS</b> No comment.			
<b>WHAT THE RESULTS MEAN</b> <b>Specimen Provenance Verified:</b> The genetic profile of this sample matches that of the reference sample.			
<b>SIGNATURE</b>			
Report Signature <b>Analyst S. Name, DNA Analyst</b>		Signature Date <b>09/19/2012</b>	
<b>TESTING MATERIALS AND METHODS</b>			

DNA Specimen Provenance Assignment (DSPA) is used to validate a specimen's provenance and purity. Concordant DSPA results are critical to ensuring accurate diagnosis of cancer or other pathological conditions. DNA is isolated from a reference specimen of known provenance and one or more diagnostic



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